



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service
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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

VIA FACSIMILE

Jules Buccieri
DG Labs
dba 7-Day Miracle Cleanse
P.O. Box 3362
Burbank, California 91504

Dear Mr. Buccieri:

We are writing to you because a review of your web site, <http://www.7dmc.com>, revealed a serious regulatory problem involving the product known as the "Expanded Vision Colon Board," which is marketed by your firm.

Under a United States law, the Federal Food, Drug, and Cosmetic Act (the Act), this product is considered to be a medical device because it is intended for use in the diagnosis or treatment of a medical condition or to affect the structure or function of the body. The law generally requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that newly introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country.

According to your web site, the Colon Board is used for the purpose of home colon cleansing. From the design, the device appears to be an enema kit, a Class I device "intended to instill water or other fluids into the colon through a nozzle inserted into the rectum to promote evacuation of the contents of the lower colon." 21 CFR 876.5210. However, the intended use of the device, as reflected in the claims on your web site, more closely resemble those for a colonic irrigation system intended for routine colon cleansing for general well being (21 CFR 876.5220(b)(2)), a Class III device for which premarket approval is required. Examples of the claims made on your web site for the Colon Board include detoxification, greater longevity, self healing, and improving health and the immune system.

Our records do not show that you obtained marketing clearance or approval before you began offering your product for sale. The kind of information you need to submit in order to obtain this clearance or approval is described on FDA's device web site at www.fda.gov/cdrh/devadvice. FDA will evaluate this information and decide whether your product may be legally marketed.

Because you do not have marketing approval or clearance from the FDA, marketing your product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is misbranded under the Act because you did not submit a section 510(k) premarket notification that shows your device is substantially equivalent to other devices that are legally marketed. Until you submit a section 510(k) premarket notification and FDA reviews it and notifies you that you may market your device, your product is also adulterated under the Act because the law requires, and you do not have, an approved premarket approval application that shows your device is safe and effective. For a product requiring premarket approval, the notification required by section 510(k) of the Act is deemed to be satisfied when a premarket approval application (PMA) is pending before the agency. 21 CFR 807.81(b).

Your Colon Board is also misbranded under section 502(o) of the Act, in that the device was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 and was not included in a list required by section 510(j).

You should know that these serious violation(s) of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary to take action on this matter now. Please let this office know what steps you have taken to correct the problem within fifteen (15) working days from the date you received this letter. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Mr. Paul Tilton, Chief, OB/Gyn, Gastroenterology and Urology Devices Branch (HFZ-332), Division of Enforcement A, Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Road, Rockville, Maryland 20850.

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Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter does not necessarily address all of the obligations you have under the law.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Larry D. Spence" followed by a large, stylized flourish.

Timothy A. Ulatowski

Director

Office of Compliance

Center for Devices and

Radiological Health

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